IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Civil Action No. 07-2339 (RMB) (JS)

WILLIAM C. JENSEN,
By and on Behalf of the United States of America, Relator

State of Massachusetts, *ex rel*
William C. Jensen, Relator

State of California, *ex rel*
William C. Jensen, Relator

State of Hawaii, *ex rel*
William C. Jensen, Relator

State of Illinois, *ex rel*
William C. Jensen, Relator

State of Florida, *ex rel*
William C. Jensen, Relator

State of New York, *ex rel*
William C. Jensen, Relator

State of Texas, *ex rel*
William C. Jensen, Relator

State of Tennessee, *ex rel*
William C. Jensen, Relator

State of Delaware, *ex rel*
William C. Jensen, Relator

State of Louisiana, *ex rel*
William C. Jensen, Relator

State of Nevada, *ex rel*
William C. Jensen, Relator

FILED IN CAMERA AND UNDER SEAL

COMPLAINT AND JURY DEMAND

District of Columbia, *ex rel*
William C. Jensen, Relator

City of New York, *ex rel*
William C. Jensen, Relator

v.

GLAXOSMITHKLINE, plc, and
GLAXOSMITHKLINE HOLDINGS
(AMERICAS) INC.,
Defendants.

Relator, William C. Jensen ("Relator" or "Jensen"), bringing this action under the False Claims Act, 31 *U.S.C.* § 3729, *et seq.*, as well as various state and municipal False Claims Acts, alleges as follows:

NATURE OF THIS ACTION

1. The Relator brings this action on behalf of the United States to recover damages and penalties under the False Claims Act, 31 *U.S.C.* § 3729, *et seq.*, (the "FCA"), and various State and municipal False Claims Acts. Defendants, GlaxoSmithKline, plc ("GSK") and GlaxoSmithKline Holdings (Americas) Inc. ("GSKH") (hereinafter "defendants"), are principally engaged in the manufacture and sale of pharmaceuticals. This action alleged that defendants defrauded the United States Government, various states and the City of New York in the course of marketing and selling pharmaceuticals to the United States Government and/or its beneficiaries.

2. Specifically, defendants have defrauded the United States Government, various states and municipalities by knowingly, willfully and intentionally engaging in a fraudulent scheme to promote the "off-label" sale (i.e., uses not approved by the Food and Drug Administration ("FDA")) to the United States government and its beneficiaries of Lexiva, the proprietary name or trademark

of the generic drug, "fosamprenvair calcium." Lexiva is defendants' primary product in the United States's HIV protease inhibitor pharmaceutical market.

3. In particular, defendants are actively promoting dangerously low-dosing of Lexiva via an illegal marketing campaign, including, upon information and belief, giving bribes, kickbacks and other incentives to doctors to prescribe Lexiva at off-label doses in order to compete in the HIV protease inhibitor market. Defendants' off-label promotional activities are causing submissions of false claims to federal agencies and programs, including, but not limited to, the Veterans Administration ("VA"), the U.S. Department of Defense ("DOD"), the U.S. Department of Corrections ("DOC"), Centers for Medicare and Medicaid Services ("CMS"), U.S. Department of Health and Human Services ("DHHS"), Railroad Retirement Board ("RRB"), Office of Personnel Management ("OPM"), Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"), State Legalization Impact Assistance Grants ("SLIAG"), and to the federal government on behalf of Medicaid, Medicare, Aids Drug Assistance Program ("ADAP"), Ryan White HIV/AIDS Program ("Ryan White") beneficiaries, and various public health service organizations.

4. FDA approved labeling requires prescribing Lexiva with specific doses of a "boosting agent," ritonavir, another protease inhibitor manufactured by Abbott Laboratories, Inc. ("Abbott"), under the proprietary name or trademark "Norvir." Prescribing Lexiva with subtherapeutic doses of ritonavir permits defendants to compete with Bristol-Myers Squibb's ("BMS") HIV protease inhibitor, Reyataz, which requires boosting with lower doses of ritonavir and Abbot's HIV protease inhibitor, Kaletra, which is co-formulated with ritonavir (a drug also manufactured by Abbott). HIV positive patients whose health care providers have been induced to prescribe Lexiva with

subtherapuetic, non-FDA-approved levels of ritonavir are at greater risk for deadly virus mutation and virologic failure resulting in full-blown AIDS and early death.

5. In addition, defendants are actively promoting the use of the HLA-5701 genetic-marker skin patch test to test for dangerous hypersensitivity reaction to abacavir sulfate, the proprietary name or trademark of which is defendants' "Epzicom," another drug defendants manufacture, market and sell for treatment of HIV infection. The FDA has not approved use of the HLA-5701 patch to detect hypersensitivity to abacavir sulfate. Notwithstanding its lack of FDA-approval for that use, defendants have instructed their HIV sales force to promote use of the HLA-5701, including, upon information and belief, giving bribes, kickbacks and other incentives in excess of the market value to doctors to prescribe the HLA-5701 patch for the off-label use in order to increase sales of Epzicom.

6. The Relator also brings this action on behalf of the United States to recover damages and penalties under the Federal Anti-Kickback Statute, 42 § 1320a-7b(b)(2).

7. William C. Jensen files this action as a Relator under the False Claims Act, 31 *U.S.C.* § 3730.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction to entertain this proceeding pursuant to 28 *U.S.C.* § 1331, 28 *U.S.C.* § 1345, 31 *U.S.C.* § 3730(b) in that the action arises under the laws of the United State of America and that claims asserted herein are brought in the name of the United States Government. Nationwide service of process is provided under 31 *U.S.C.* § 3732(a).

9. This Court has personal jurisdiction over defendants pursuant to 31 *U.S.C.* §

3732(a) as the defendants transact or have transacted business in the District or has committed acts proscribed by 31 *U.S.C.* § 3729 within the District.

10. This court has pendent jurisdiction over Relator's claims under various state and municipal whistleblower laws.

11. Venue is proper in this District under 31 *U.S.C.* § 3732(a) and 28 *U.S.C.* § 1391(b) and (c). Defendants transact business within this District.

PARTIES

12. Relator, William C. Jensen, is a citizen of the State of New Jersey with residence at 543 West Kings Highway, in the Borough of Audubon, County of Camden, State of New Jersey. During all times relevant to this cause of action, Relator has been an employee of defendant and continues in that capacity.

13. Relator brings this action on behalf of the United States of America.

14. Defendant GSK is a corporation headquartered in London, the United Kingdom, with its United States corporate headquarters in Philadelphia, Pennsylvania, and principle places of business in Research Triangle Park, North Carolina and prescription product manufacturing sites in Bristol, Tennessee, King of Prussia, Pennsylvania, and Zebulon, North Carolina.

15. Defendant GSK describes itself in its 2006 annual report "as a major global healthcare group engaged in the creation, discovery, development, manufacture and marketing of pharmaceutical and consumer health-related products."

16. Defendant GSK regularly transacts business in this judicial district.

17. In 2006, GSK employed more than 102,000 employees worldwide including approximately 24, 000 employees in the United States.

18. In 2006, defendant GSK had revenues of approximately $225 million for sales its HIV anti-viral drug, Lexiva (including its predecessor, Agenerase), $136 million of which comprised sales in the United States.

19. The defendant GSKH is a division of GSK and is a trade name through which GSK markets its pharmaceutical products and services in the United States of America. GSKH is incorporated in Wilmington, Delaware.

20. GSK's HIV Division employees approximately 146 employees in the United States. Approximately 111 of those 146 employees, are HIV Clinical Specialists, members of GSK's HIV drug sales force.

21. GSK's HIV Division is the most profitable of GSK's pharmaceutical divisions doing approximately $1.7 billion in annual gross sales.

FACTUAL BACKGROUND

22. Relator has a master's degree in business administration from St. Joseph's University and a bachelor of science degree from The College of New Jersey.

23. Relator has been employed by defendant GSK for twelve (12) years.

24. Currently, Relator is employed in GSK's HIV Division in the position Senior Executive Clinical Specialist. As a Senior Executive Clinical Specialist, Relator is responsible for the marketing and sale of defendants' HIV drugs to healthcare providers who prescribe defendants' drugs to HIV patients. Relator is responsible for the following territories: Philadelphia, Pennsylvania and Central and Southern, New Jersey.

25. Relator has witnessed the defendants engaging in widespread and on-going fraud against the federal government, including, but not limited to agencies and programs of the VA,

DOD, DOC, CMS, DIIIIS, RRB, OPM, CHAMPUS, SLIAG and to the federal government on behalf of Medicaid, Medicare, ADAP, and Ryan White beneficiaries, and various public health service organizations.

26. Relator has objected to defendants' widespread fraud against the United States Government to no avail. Despite internal statements to the contrary from his direct supervisor, Michelle Rodriguez, GSK Regional Sales Director-HIV, Relator has witnessed and has knowledge of defendants' on-going scheme to fraud the United States Government.

27. As a result of his position with defendants, Relator has substantial direct contact with healthcare providers who prescribe HIV drugs to HIV-positive patients. Relator also has substantial direct contact with HIV-positive patients, many of whom are the beneficiaries of Medicaid, Medicare, ADAP, Ryan White and other federal reimbursement for pharmaceutical coverage for treatment with HIV medications.

(OFF-LABEL MARKETING OF LEXIVA)

A. <u>The Regulatory Scheme Regarding Off-Label Use of Pharmaceuticals</u>.

28. The FDA prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. *See*, 21 U.S.C. § 331(c) and (d). If the manufacturer intends to promote a drug for new uses in addition to those already approved, the materials on off label uses must meet certain stringent requirements and the manufacturer must resubmit the drug to the FDA testing and approval process. 21 U.S.C. § 360(a)(a)(a), *et seq*.

29. Medicaid, like other federal programs, is permitted to reimburse federal beneficiaries only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10).

30. Covered outpatient drugs do <u>not</u> include drugs that are "used for medical

indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(3).

31. A "medically accepted indication" is a use "which is approved under the Federal Food, Drug and Cosmetics Act" or which is included in specified drug compendia. 42 U.S.C. § 1396r-8(K)(6); *id.* § 1396r-8(g)(1)(B)(i).

32. Defendants have intentionally caused the submission of fraudulent claims to United States Government for reimbursement to federal beneficiaries for Lexiva, defendants' primary HIV protease inhibitor for uses, that have not been approved by the FDA and are not included in federally-approved drug compendia.

B. Defendants' Illegal Marketing and Promotion of Off-Label Use of Lexiva

(1)FDA Approved Dosage of Lexiva with Boosting Agent Ritonavir

33. Lexiva (fosamprenavir calcium) is manufactured, marketed and sold by defendants, a protease inhibitor for the treatment of HIV.

34. The fosamprenavir in Lexiva is rapidly converted to amprenavir, an inhibitor of HIV-1 protease. In therapy-naïve patients, the FDA has approved Lexiva to be prescribed at 1400mg twice per day without ritonavir. The FDA requires that **all** other doses of Lexiva be prescribed in combination with a **"boosting agent" of at least 200mg daily of Norvir (ritonavir)**, a protease inhibitor manufactured by Abbott. In protease-inhibitor experienced patients, Lexiva is not approved for prescription without at least 200mg of ritonavir daily.

35. Specifically, according to "**DOSAGE AND ADMINISTRATION**" on GSK's Lexiva label, the FDA has approved the following dosages:

> LEXIVA Tablets may be taken with or without food. The recommended oral does of LEXIVA, alone or in combination with ritonavir, is as follows:
>
> **Therapy-Naïve Patients:**

- LEXIVA 1,400 mg twice daily (without ritonavir)
- LEXIVA 1,400 mg once daily plus ritonavir 200 mg once daily
- LEXIVA 700 mg twice daily plus ritonavir 100 mg twice daily
  The twice-daily plus ritonavir dose is supported by pharmacokinetic and safety data (see CLINICAL PHARMACOLOGY and ADVERSE REACTIONS).

Protease Inhibitor-Experienced Patients:

- LEXIVA 700 mg twice daily plus ritonavir 100 mg twice daily.
  Once-daily administration of LEXIVA plus ritonavir is not recommended in protease inhibitor-experienced patients (see Description of Clinical Studies).

36. According to "**INDICATIONS AND USAGE**" on GSK's Lexiva label:

"**[o]nce daily administration of LEXIVA plus ritonavir is <u>not</u> recommended for protease inhibitor-experienced patients.** (emphasis added.)

37. According to "**Description of Clinical Studies: Protease Inhibitor-Experienced Patients: Study APV30003** " on GSK's Lexiva label:

"Once-daily administration of Lexiva plus ritonavir is **not recommended** for protease inhibitor-experienced patients. Through week 48, 50% and 37% of patients receiving LEXIVA/ritonavir once daily had plasma HIV-1 RNA <400 copies/mL and <50 copies/mL respectively.

38. Lexiva, when boosted with Norvir (ritonavir), is known as the "boosting dose" of Lexiva. Boosting with Norvir (ritonavir) increases the amount of Lexiva in a HIV-patient's body. Lexiva without Norvir (ritonavir) may be less effective due to decreased blood levels of amprenavir in a HIV positive patient's body.

39. In order to compete with BMS' HIV protease inhibitor, Reyataz, which requires boosting with only 100 mg of Norvir (ritonavir) and Abbott's Kaletra, which is made with ritonavir built into the Kaltera capsule, defendants have marketed Lexiva for use with only a 100 mg dose of Norvir (ritonavir), a use that is <u>not</u> FDA approved. Lexiva, when sold for such

usages, may not be paid for by federal programs such as Medicaid and/or Medicare.

(2) Annual Federal Funds Spent On Care of HIV Positive Patients

40. Defendants control approximately 15% of the HIV protease inhibitor pharmaceutical market in the United States. The market is expanding as the number of HIV-positive patients in the United States increases.

41. Currently, there are approximately 1 million people in the United States living with HIV. *See*, http://www.cdc.gov/hiv/25.htm. As the epidemic continues, an estimated 40,000 additional people are infected with HIV in the United States each year. *Id.* African-American men and women are among the hardest-hit populations in the United States and account for 50% of all new HIV diagnoses in the nation. *Id.*

42. According to the United States Department of Health and Human Services, about 44% of HIV patients depend on Medicaid or Medicare combined with Medical to pay for HIV treatment and 6% depend on Medicare alone. More than $7 billion is spent each year on Medicaid, Medicare , the Department of Veterans' Affairs and the Ryan White CARE ACT to treat people with HIV disease. *See*, http://www.ahrq.gov/news/focus/fochiv.htm.

43. In other words, the United States Government pays for at least 50% of the cost of HIV care in the United States.

44. At those rates, at least 50% of defendants' sales of Lexiva were reimbursed by Medicaid and/or Medicare. Of the $136 million of U.S. sales of Lexiva in 2006, therefore, approximately $68 million was reimbursed by the United States Government.

45. Based on relator's personal experience, as well as information and belief, greater than 50% of physicians prescribe Lexiva for off-label use as a direct result of defendants' above-

described unlawful marketing and promotional efforts. Thus, no less than $34 million per annum of federal reimbursements for Lexiva are for unauthorized off-label use.

46. Defendants have been engaged in the aforesaid fraudulent practice for a substantial period of time.

(3) GSK's Extensive And On-Going Campaign to Promote Off-Label Use of Lexiva

47. For a substantial period of time, in order to compete for market share and to try to expand their overall business, defendants have been illegally promoting the "off-label" subtherapeutic dosing of Lexiva by exaggerating and/or making fraudulent claims concerning the safety and efficacy of Lexiva at off-label doses. Defendants have given doctors incentives to prescribe non-approved, subtherapeutic doses of Lexiva with ritonavir at levels that likely increase patients risks of virus mutation, full-blown AIDS and early death.

48. In an extensive and far-reaching effort to promote off-label use of Lexiva, defendants have developed an aggressive, unlawful marketing campaign in which defendants enter into consulting, speaking and/or other personal service agreements for substantial sums of money (in excess of market value) with HIV and infectious disease specialists, physicians, and researchers, to perform consulting, research and lecture services for the express purpose of encouraging physicians to prescribe off-label doses of Lexiva. Defendants' lecturers address thousands of medical doctors, pharmacological doctors, nurse practitioners and physician's assistants in the United States each year.

49. As a result, increased prescriptions for off-label doses of Lexiva cause the filing of false claims for reimbursement by the federal government through programs including, but not limited to, Medicare, Medicaid, ADAP, VA, DOD, DOC, CMS, DHHS, RRB, OPM,

CHAMPUS, SLIAG, and federal prison medical programs.

50. The impact of defendants' Lexiva "off-label" marketing campaign upon the HIV population in the United States is deadly. According to Relator's experience and knowledge, boosting Lexavir with off-label doses of ritonavir results in low levels of protease inhibitors in patients' blood. As a result, patients given non-FDA-approved doses of Lexiva/ritonavir experience virologic failure in which a patient's viral load exceeds 400 copies and his/her CD4+ cell count falls to dangerously low levels creating an environment in which the HIV virus can mutate into an untreatable, deadly strain, causing the patient to enter end-stage AIDS, and suffer early death.

51. Defendants have developed a nationwide speakers program to promote the off-label use of Lexiva. In furtherance of their speaker's program, defendants have an "approved list of trained speakers" from which its employees, including HIV clinical specialists and other members of the GSK's HIV and sales divisions, are encouraged to draw speakers, who promote off-label use of Lexiva. Defendants have approximately forty (40) "approved" national speakers and 120 "approved" regional speakers. The national speakers train the regional speakers.

52. As of 2007, defendants pay national speakers up to $150,000.00 per year and regional speakers up to $35,000.00 per year. Speaking fees do not include fees for services including, but not limited to, fees for serving on advisory boards, creating promotional materials, or training other speakers.

53. Defendants hire the approved speakers (HIV/infectious disease specialists, physicians and researchers) for the express purpose of exaggerating and/or making fraudulent claims concerning the safety and efficacy of Lexiva at off-label doses. In return, defendants

reward the approved speakers with substantial lecture, research and consulting fees.

54. Among defendants' national approved speakers, those who lecture regarding off-label uses of Lexiva most often are the most highly utilized by defendants. These speakers include Andrew D. Luber, Pharm. D., of Voorhees, New Jersey, Kimberly Smith, D.O., of Chicago, Illinois, Derek M. Fine, M.D., of Baltimore, Maryland and Michael J. Harbour, M.D. of Stanford, California.

55. By way of example, and without limitation, defendants have paid Dr. Luber, a renowned HIV researcher who has performed numerous clinical trials for GSK and Vertex, the company which created Lexivar – **hundreds of thousands of dollars** to actively promote off-label use of Lexivar through lectures to health care providers who treat HIV positive patients.

56. For instance, at defendants' request, in or about October 2006, Dr. Luber gave a lecture to physicians at the Atlantic City Medical Center in Atlantic City, New Jersey, on an off-label 24-week clinical trial for Lexiva titled "ALERT." In or about December 2006, Dr. Luber gave a similar lecture to physicians at Philadelphia Fight, a comprehensive AIDS service organization which provides, among other things, primary care to HIV patients.

57. Dr. Luber, a resident of Voorhees, New Jersey, maintains his professional office in Los Angeles, California.

58. In 2006, upon information and belief, defendants paid Dr. Luber approximately $155,000.00 in lecture fees only for more than sixty (60) lectures. This sum excludes monies defendants paid Dr. Luber for consulting and research.

59. Currently, defendants pay Dr. Luber a minimum of $2,500.00 per lecture or clinical roundtable dinner discussion. As of June 1, 2007, Dr. Luber will have completed thirty-

six (36) lectures for defendants for approximately $90,000.00. Presently, Dr. Luber is scheduled to lecture on Lexiva in Dallas, Texas, on May 18, 2007 and in New Bedford, Massachusetts and Providence, Rhode Island on May 23, 2007.

60. In 2006 and 2007, Dr. Luber has lectured on Lexiva on the following dates: 1/6/06, 1/26/06, 1/27/06, 3/7/06, 3/15/06, twice on 3/16/06, 3/17/06, twice on 3/28/06, 6/20/06, 6/21/06, twice on 6/22/06, 7/6/06, 8/23/06, 9/7/06, twice on 9/12/06, twice on 9/13/06, 10/26/06, 11/14/06, twice on 11/15/06, 11/27/06, 11/28/06, 11/29/06, 11/30/06, 1/2/07, 2/20/07, 3/5/07, twice on 3/6/07, 3/7/07, twice on 3/8/07, 3/9/07, 3/13/07, twice on 3/14/07, twice on 3/15/07, 3/16/07, twice on 3/27/07, and twice on 3/28/07. Dr. Luber has conducted Roundtable Discussions on Lexiva on the following dates: 3/3/06, 7/6/06, 8/22/06, 8/23/07, 9/14/06, 9/20/07, 11/27/06, 11/29/06, twice on 2/5/07, 2/20/07, 3/5/074/4/07, and will be conducting another on 9/6/07.

61. Relator has witnessed Dr. Luber promote the off-label use of Lexia on, by way of example and not by limitation, on March 7, 2006, at the HIV Clinic at Drexel University in Philadelphia, Pennsylvania; on April 6, 2006, at the Porterhouse Steak Restaurant in Cherry Hill, New Jersey; on August 7, 2006, at the Garden State Infectious Disease Associates, in Voorhees, New Jersey; and on September 7, 2006, at the POD Restaurant in Philadelphia, Pennsylvania.

62. In addition to lectures, Dr. Luber writes proactive discussion slides promoting off-label use of Lexiva for use by defendants' national and regional speakers. Every healthcare provider in defendants' Lexiva database are provided with a copy of Dr. Luber's slides including information on off-label use of Lexiva with subtherapeutic doses of ritonavir. Dr. Luber's slide program specifically addresses the off-label Alert trial.

63. Mr. Luber has made clear his commit to defendants' aggressive campaign to market off-label use of Lexiva.

64. On October 23, 2006, at 11:26 a.m., Relator e-mailed Dr. Luber:

> Andy,
>
> . . . . I have a lecture opportunity at Bobby Flay Steakhouse in Atlantic City on Monday, November 13th @ 7:00 p.m. Would you be interested in speaking on Lexiva/Epzicom (Solo and Klean) [FDA approved drug trials]

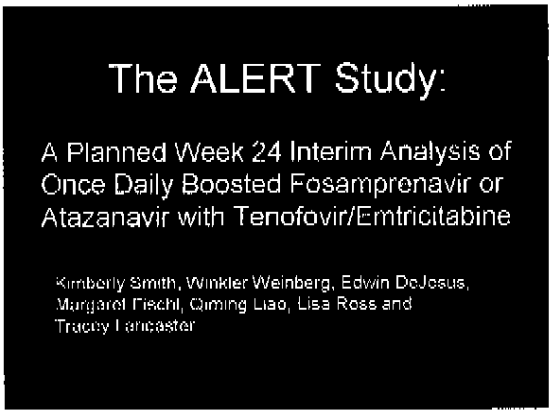
65. In response, Mr. Luber e-mailed Relator on October 24, 2006 at 3:56 p.m.:

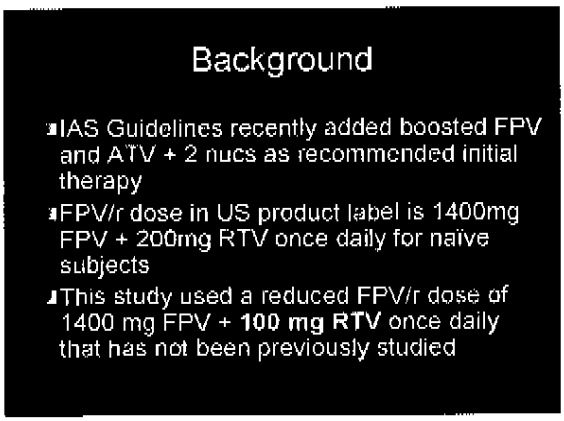
> . . . . Solo??? Who the hell talks about SOLO anymore???? KLEAN and Alert are the studies you want to highlight and open up for discussion (e.g. how are these agents really different, if at all?)

66. ALERT is a non-FDA approved study of Lexiva with boosting of only 100 mg of ritonavir, an off-label dosage. A Powerpoint presentation on the ALERT study created by, among others, its lead investigatory author and defendants nationally approved Lexiva speaker, Dr. Kimberly Smith, M.D., states specifically:

- FPV/r dose in US is 1400mg FPV + 200mg RTV once daily for naïve subjects.
- This study used a reduced FPV/r dose of 1400mg FPV + **100mg RTV** once daily that has not been previously studied.

67. Excerpts of the ALERT Powerpoint slideshow are as follows:





68. Relator has objected to Mr. Luber's off-label Lexiva lectures. Upon receipt of the aforementioned October 24, 2006 e-mail from Dr. Luber, Relator forwarded Dr. Luber's responses to his direct supervisor, Michelle Rodriguez, Regional Sales Director in defendants' HIV Division, with the following message:

> Michelle,
> I received this reply from Andy Luber. I am concerned that his response was a little inappropriate to my request to do an "on-lable [sic]" lecture! What action should I take? Would it be in my best interest to find another speaker and gracefully step away if possible? I initially requested Gary Frost but he has a prior commitment.

69. Three days later, on October 27, 2006, Ms. Rodriguez responded to Relator's e-mail, in which she suggested that Dr. Luber, a renowned HIV expert and one of defendants' primary national speakers, was "confused," and asked Relator to call her to discuss. Specifically, Ms. Rodriguez stated:

> Bill– call me to discuss. I think Andy may just be confused and thinking that Alert has been approved as data for us to discuss. We need to clarify that for him that is not the case asap. Let's discuss.

70. Thereafter, defendants directed Relator to use Dr. Luber for a lecture in December

2006 at Philadelphia Fight. Relator refused to use Dr. Luber for the Philadelphia Fight lecture.

71. On or about December 6, 2006, Relator met Dr. Luber at a conference at which Relator told Dr. Luber, "I'm very concerned about what you and PharmDs like you are doing," referring to marketing and promoting off-label use of Lexiva. In reply, Dr. Luber told Relator that defendants' management "get's it, but its people like you that has to get that this is the direction we're going."

72. Defendants rescheduled the Philadelphia Fight lecture to take place in January 2007, while Relator was on vacation, and hired Dr. Luber to give the lecture.

73. The primary author/investigator of the ALERT trial is Kimberly Smith, MD an Associate of John Stroger Hospital of Cook County in Chicago, Illinois. Dr. Smith is also on defendant GSK's approved list of national Lexiva speakers.

74. Dr. Smith also routinely promotes the off-label dose of Lexiva with subtherapeutic ritonavir and the ALERT study. Relator has witnessed Dr. Smith lecture on off-label dosing of Lexiva. Dr. Smith does not even disclose to those whom she lectures that dosages of Lexiva-ritonavir in the ALERT trial are not FDA approved and, therefore, off-label.

75. Among others, Marlon Pittman, defendant GSK Vice President of HIV Sales, Yolanda Shaffer, GSK Market Developmental Director for GSK's HIV Division and Relator's Direct Supervisor, Michelle Rodriguez, Regional Sales Director for GSK's HIV Division, have encouraged defendants' use of Drs. Luber and Smith and other GSK approved lecturers, to promote Lexiva for off-label use.

76. Defendants hired Drs. Luber and Smith to promote off-label use of Lexivar knowing they were doing so in order to compete with BMS' HIV drug Reyataz and Abbott's

HIV drug Kaletra.

77. Defendants' off-label promotion has been successful. As a result, physicians have been prescribing off-label doses of Lexiva with ritonavir to individuals who then submit the prescriptions to pharmacies for reimbursement by federal benefit programs including Medicare, Medicaid and ADAP.

78. Drs. Luber and Smith's "off-label" Lexiva lectures, often referencing the ALERT trial, have induced hundreds of healthcare providers to prescribe "off-label" doses of Lexiva. By way of example, and without limitation, healthcare provider, James T. Dwyer, DO, of Garden State Infectious Disease Associates, 709 Haddonfield Berlin Road, Voorhees, New Jersey 08043 has advised Relator that as a result of Dr. Luber's lectures, he prescribed "off-label" sub therapeutic doses of Lexavir with ritonavir to at least two (2) of his HIV-positive patients. According to Dr. Dwyer, both patients experienced virologic failure in the form of deadly protease mutations. As a result, Dr. Dwyer is likely unable to find another on-label pharmaceutical regimen to successfully treat these patients.

79. By way of example, and without limitation, healthcare provider Sofia Sherman-Weber, DO, of Croter-Chester Medical Center, One Medical Center Boulevard, Upland, PA 19013, has advised Relator that she has followed "the Company's [GSK's] advice" and prescribed Lexiva with only 100mg of ritonavir as a booster agent.

80. GSK has also actively promoted "off-label" lower dosing of Lexiva-ritonavir by rewarding kickbacks to physicians for prescribing large quantities of GSK's Lexiva.

81. As a direct result, knowing it is against the law, GSK has promoted off-label use of Lexiva-ritonavir with the intent and purpose to cause Medicare and Medicaid to reimburse

Medicare and Medicaid beneficiaries for claims submitted for off-label Lexiva use.

C. Defendants' Off-Label Promotion of the HLA-5701 Genetic Marker Skin Patch Test.

82. Defendants have also actively promoted the off-label prescription of a genetic-marker skin patch test, HLA-5701, for a use for which the FDA has not granted its approval.

83. Defendants have directed their HIV sales force, including, but not limited to, Relator, to advise physicians that they should request the HLA-5701 skin patch test to test for a patient's potential hypersensitivity reaction to abacavir sulfate, a primary component of another of defendants' HIV-drugs, Epzicom. Abacavir sulfate has been associated with serious and sometimes fatal hypersensitivity reactions in HIV patients.

84. The FDA has not approved the HLA-5701 skin patch for use for testing for hypersensitivity reaction to abacavir sulfate, the use for which defendants have directed their sales force to promote and market it.

85. By way of example, and not limitation, at defendants' recent (April 16-19, 2007) national sales meeting in Naples, Florida, at which defendants' entire sales force was present, Cindy Brothers, Associate Director of Infectious Disease at GSK, encouraged defendants' HIV sales force to, in turn, encourage physicians to request the HLA-5701 skin patch test for off-label use.

86. In addition, defendant GSK's Director of Marketing, Tom Laugherty, addressed the HIV sales in Naples, Florida, and encouraged off-label use of the HLA-5701 skin patch test.

87. Drs. Denise Sutherland Phillips and Jaime Hernandez are actively lecturing on defendants' behalf regarding the off-label use of the HLA-5701 skin patch test.

88. In late 2006, Relator attended a presentation at the Water Works Restaurant in

Philadelphia, Pennsylvania, at which time Dr. Hernandez pro-actively showed slides of the HIC positive patients using the HLA-5701 skin patch test for off-label uses.

89. In fact, Relator, in his capacity as a Senior Executive Clinical Specialist with defendants, has personal knowledge that the HLA-5701 skin patch test has not been clinically proven to properly detect hypersensitivity reaction to abacavir sulfate in HIV patients. Thus, a patient who received a false negative on the HLA-5701 skin patch test could experience a severe, life-threatening or even fatal hypersensitivity reaction to oral administration of Epzicom.

90. Defendants have illegally marketed and promoted the HLA-5701 skin patch test in order to increase sales of its HIV drug, Epzicom.

91. As a result physicians, increased prescriptions for off-label prescriptions for the HLA-5701 skin patch test have caused the filing of false claims for reimbursement by the federal government through programs including, but not limited to, Medicare, Medicaid, ADAP, VA, DOD, DOC, CMS, DHHS, RRB, OPM, CHAMPUS, SLIAG, and federal prison medical programs

(CONSPIRACY TO OFFER TO PAY ILLEGAL REMUNERATION)

A. Corporate Organization of Defendants' HIV Business Unit

92. Relator is a Senior Executive Clinical Specialist, in defendants' HIV Division. His job is to sell defendants' HIV drugs.

93. Relator is one of approximately 110 clinical specialists in defendants' sales force. Joseph N. Avallone is also a Senrior Executive Clinical Specialist.

94. Relator reports to Michelle Rodriguez, defendant GSK's Regional Sale Director, HIV Division. She is primarily responsible for defendants' business in the northeastern United

States.

95. Ms. Rodriguez reports to Marlon J. Pittman, Vice President of Sale in Defendants' HIV Division.

96. Mr. Pittman reports to Peter Herr, a GSK Senior Vice President who is head of defendant GSK's HIV Business Unit. Mr. Herr is responsible for managing GSK's $1.7 billion annual sales of HIV drugs.

97. Mr. Herr reports to Chris Viehbacher, President of defendant GSK.

98. In addition, Yolanda Shaffer and Vera Parker are Directors of Marketing Development for GSK's HIV Division. Together, they work with Tom Laugherty, GSK's HIV Division Director of Marketing, to market and promote GSK's HIV drugs. Ms. Shaffer, Ms. Parker and Mr. Laugherty report to Mr. Pittman.

B. Federal Anti-Kickback Statute

99. The federal Medicare/Medicaid Anti-Kickback Statute provides that:

> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
> *See* 42 U.S.C. § 1320a-7b(b)(2).

C. Defendants' Anti-Kickback Conspiracy

(1) Kickbacks to Physicians for Prescribing Lexiva

100. For a substantial period of time, the exact dates being unknown to Relator, in the District of New Jersey and elsewhere, Defendants, and others known and unknown to Relator, including Peter Herr, Marlon Pittman, Tom Laugherty, Yolanda Shaffer, Vera Parker, Joseph N. Avallone, and Michelle Rodriguez, knowingly and willfully combined, conspired, and agreed to commit an offense against the United States, to wit, 42 *U.S.C.* § 1320a-7b(b)(2) *et seq.*, by knowingly and willfully offering and paying remuneration, directly and indirectly, overtly and covertly, in cash and in kind, to physicians to induce them to refer individuals, including Medicaid patients and beneficiaries of other federal programs, to pharmacies for the furnishing of the drug Lexiva, for which payments were made in whole and in part under federal and state Medicaid programs.

101. It was the purpose of this conspiracy that defendants targeted physicians who prescribe Lexiva and offered these physicians financial incentives in order to obtain a prescription volume that would advance the sales goals of defendants' HIV pharmaceutical products in order to permit it to compete with BMS' HIV protease inhibitor, Reyataz, Abbott's protease inhibitor, Kaletra, and/or overtake the United States market in HIV protease inhibitors.

102. Upon information and belief, defendants have used, among other things, lecture fees, consulting contracts, research studies, bribes and other illegal inducements, in excess of market value, to cause physicians to prescribe defendants' HIV pharmaceutical products over defendants' competitors' HIV pharmaceutical products.

103. By way of example, and without limitation, on March 16, 2004, Jeanine Mancuso, MSW, Grant Administrator for Access One, Inc., an organization located at 730 Shore Road in Somers Point, New Jersey, that describes itself as one providing comprehensive medical care and

social services to individuals and living with HIV/AIDs in southern New Jersey wrote the following correspondence to Joseph Avallone, Sr. Executive Clinical Specialist, with defendant GSK:

> Glaxo Smith Kline
> Joseph Avallone
> 114 Hazleton Terrace
> Mullica Hill, NJ 08062
>
> Dear Joseph Avallone:
>
> On behalf of the Board of Directors, staff and patients of Access One, infected with HIV/AIDS, thank you for your continued support throughout the years.
>
> Please accept this letter of request for a grant for the amount of $3,500.00, made payable to Access One, Inc. Access One will be sponsoring a HIV/AIDS patient education program on October 22, 2004. Local physicians and consumers will be invited to the event.

Access One, Inc., is a non-profit AIDS organization that provides comprehensive medical care and social services to people living with HIV/AIDS in Atlantic, Cape May and Cumberland Counties. This grant will be used to provide educational materials and insight to patients in an effort to improve HIV patient care.

> I have enclosed our non-profit status and our tax ID# is 22-3618547. If you need any further information please contact me at (609) 927-6662 or via fax (609) 927-2942.

104. Upon information and belief, Mr. Avallone certified that Access One, Inc., the payee organization on the above-referenced grant request, was a "non-customer" which defendants define as one who does not buy, sell or write prescriptions for GSK products.

105. Mr. Avallone, an employee of defendant GSK, is the co-founder and Chairman of the Board of Directors of Access One, Inc.

106. The offices of Access One, Inc., are located within the private medical offices of Christopher J. Lucasti, D.O., License No. 52019, also located at 730 Shore Road in Somers

Point, New Jersey. Dr. Lucasti practices infectious disease medicine.

107. Dr. Lucasti performs clinical trials of medication for the United States government including the National Institutes of Health and the FDA.

108. Dr. Lucasti's office is identified as a "Clinical Trials Call Center" for defendant GSK.

109. Dr. Lucasti is recruiting HIV-positive patients to participate in a study sponsored by defendant GSK: A Study of an Investigational Regimen Combining FDA Approved HIV Drugs in HIV-Infected Subjects Clinical Government Trials Identifier NCT00363142. The study's official title is, "A Phase IIIB, Randomized, Open-Label, Parallel Group, Multi-Center, Non-Inferiority, 24-Week Study to Evaluate the Safety, Efficacy and Tolerability of Switching From a 200mg Ritonavir-Boosted Regimen of LEXIVA (700mg/100mg BID or 1400mg/200mg QD) to a Once-Daily, 100mg Ritonavir-Boosted Regimen of LEXIVA (1400mg/100mg QD)." The stated purpose of the 24-week study is "to evaluate the efficacy and safety of a once-daily ritonavir-boosted fosamprenavir regimen (1400mg/100mg QD) to a 200mg ritonavir-boosted fosamprenavir regimen administered either twice-daily or once-daily." *See* http://clinicaltrials.gov/show/NCT00363142.

110. Dr. Lucasti has also recruited patients to participate in the HIV study: The Role of Ampligen in Strategic Therapeutic Intervention (STI) of HAART - Clinical Trials Government identifier NCT00035893. *See* http://clinicaltrials.gov/ct/show/NCT00035893;jsessionid=2A1917A00F026335AF7A100448F35243?order=36.

111. Upon information and belief, Access One steers HIV positive patients to Dr.

Lucasti in return for financial kickbacks, in excess of market value, from GSK.

112. Nearly 25 % of the prescriptions Dr. Lucasti writes for HIV pharmaceuticals are for defendants' HIV protease inhibitor Lexiva. Upon information and belief, the majority of Dr. Lucasti's HIV-positive patients are recipients of federal beneficiaries including, but not limited to, recipients of Ryan White funds.

113. Dr. Arthur Leroy Williams, of Philadelphia, Pennsylvania, is a physician with the Philadelphia Department of Health. Thirty-three (33) out of every 100 HIV protease inhibitor prescriptions that Dr. Williams writes are for Lexiva. Upon information and belief, defendants pay kickbacks and other financial remuneration, in excess of market value, to Dr. Williams in exchange for his writing a high volume of Lexiva prescriptions.

114. Dr. Helena KwaKwa, an infectious disease doctor and the Director of Philadelphia Health Department, treats indigent patients in Philadelphia many of whom are beneficiaries of federal and state healthcare programs. Dr. KwaKwa treats HIV-positive patients at eleven (11) satellite clinics throughout Philadelphia. Dr. KwaKwa rotates through clinics and treats infectious diseases including HIV. 26 % of prescriptions Dr. KwaKwa writes for HIV protease inhibitors are for Lexiva.

115. Dr. KwaKwa is also on defendants approved national speaker list for Lexiva. Dr. KwaKwa lectures around the United States on Lexiva during which she relies upon Dr. Luber's clinical scenario slides for subtherapeutic dosing of Lexiva. Upon information and belief, defendants pay kickbacks and other financial remuneration, in excess of market value, to Dr. KwaKwa in exchange for her writing a high volume of Lexiva prescriptions.

116. Dr. Nigahus Karabulut, whose office is located at 413 Hillcrest Avenue, Trenton,

New Jersey operates a federally-funded office to treat HIV-positive patients. His funds are provided primarily through the Ryan White program. Dr. Karabulut is paid directly with Ryan White grant funds of approximately $1.7 million. The majority of Dr. Karabulut's patients are indigent and federal benefits recipients. Nearly 37 % of prescriptions of Dr. Karabulut writes for HIV protease inhibitors are for Lexiva.

117. Upon information and belief, those physicians have, in fact, been induced to prescribe GSK's HIV pharmaceutical products at "off-label" doses and have certified to Medicare, Medicaid and ADAP that they have not violated the anti-kickback scheme of FCA.

118. Defendant GSK has paid unduly large sums of money, in excess of market value, to physicians for, *inter alia,* lecture fees in order to induce those to prescribe GSK's HIV pharmaceutical products.

119. Upon information and belief, those physicians have, in fact, been induced to prescribe GSK's HIV pharmaceutical products at "off-label" doses and have certified to Medicare, Medicaid and ADAP that they have not violated the anti-kickback scheme of FCA.

120. As a direct result, increasing numbers of Medicare, Medicaid and ADAP beneficiaries are using Lexiva-rivonavir at dangerously low doses.

121. Some of these beneficiaries are receiving HIV treatment at, among other places, Philadelphia Veteran's Hospital, through the Philadelphia Health Department and through federal and state prisons.

(2) Kickbacks for Research Studies

122. Upon information and belief, on or about October 18, 2006, GSK employee Joseph Avalone, GSK consultant and lecturer, Andrew D. Luber, Pharm.D., have conducted

meetings with Dr. Karam Mounzer, Director of Philadelphia Fight, a comprehensive AIDS service organization, and Dr. Halena KwaKwa, Director of the Philadelphia Health Department, to solicit collaborative research studies with the understanding that GSK would pay for kickbacks to these organizations. GSK Regional Director Michelle Rodriguez had knowledge of this meeting.

123. Upon information and belief, South Jersey Infectious Disease of Somers Point, New Jersey to solicit collaborative research studies with the understanding that GSK would pay for kickbacks to this organization.

COUNT ONE

(FEDERAL FALSE CLAIMS ACT)

124. This is a *qui tam* civil action brought by Relator and the government of the United States to recover treble damages and civil penalties under 31 *U.S.C.* § 3729(a) of the False Claims Act.

125. 31 *U.S.C.* § 3729(a) provides, in relevant part, liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval (emphasis added);

(2) knowingly makes, uses, or causes to be used, a false record or statement to get a false or fraudulent claim paid or approved by the Government (emphasis added);

(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

126. Defendants violated 31 *U.S.C.* § 3729(a) by conspiring to cause and by causing false claims to be made, used and then presented to the United States Government in connection

with their fraudulent and illegal practices.

127. The United States Government, by and through Medicare, Medicaid, ADAP, DOD, DOC, CMS, DHHS, RRB, OPM, CHAMPUS, SLIAG and the VA, and other Federal agencies and Public Health Services entities, and unaware of defendants' fraudulent and illegal practices, paid directly or indirectly for off-label prescriptions for drugs manufactured, marketed and promoted by defendants.

128. Had the United States Government known that defendants were marketing and promoting off-label doses and uses of Lexiva and HLA-5701, it would not have paid directly or indirectly for these drugs.

129. Compliance with applicable drug marketing and promotion laws and other federal and state laws cited herein was an implied, and upon information and belief, also an expressed condition of payment of claims submitted to the United States government in connection with defendants' fraudulent and illegal practices.

130. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to § 3730(b) on behalf of himself and the United States Government.

131. As a result of defendants' violations of 31 *U.S.C.* § 3729(a), the United States Government has suffered enormous financial loss.

COUNT TWO

(FEDERAL ANTI-KICKBACK STATUTE)

132. Relator repeats and realleges each allegation contained in County One above

as if fully set forth herein.

133. 42 *U.S.C.* § 1320(a)-7b(b)(2) provides:

> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person–
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

134. Defendant violated 42 *U.S.C.* § 1320(a)-7b(b)(2) by knowingly and willfully offering to pay renumeration, in excess of market value, (including an kickbacks, bribes, or rebates), directly or indirectly, overtly or covertly, in cash or in land, to any person to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program.

135. Had the United States Government known that defendants were paying kickbacks and/or bribes, in excess of market value, in order to obtain referrals for services for which payment would be made in whole or in part, to a federal healthcare program, it would not have paid directly or indirectly, for those claims.

136. Relator is a private person with direct and independent knowledge if the allegations of this Complaint, who has brought this action pursuant to 42 *U.S.C.* § 1320(a)-7b(b)(2).

137. As a result of defendants' violations of 42 *U.S.C.* § 1320(a)-7b(b)(2), the United

States Government suffered substantial financial loss.

COUNT THREE

(MASSACHUSETTS FALSE CLAIMS ACT)

138. Relator repeats and realleges each allegation contained in Counts One and Two above as if fully set forth herein.

139. This is a *qui tam* action brought by Relator and the State of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Ann. 12 § 5(A) *et seq*.

140. Mass. Gen. Laws Ann. 12 § 5B provides liability for any person who:

1. knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

2. knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;

3. conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;

4. is a beneficiary of an inadvertent submission of a false claim to the common wealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim.

141. Defendants violated Mass. Gen. Laws Ann. 12 § 5B and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Massachusetts for a substantial period of time by off-label marketing and promotion of their products.

142. The State of Massachusetts, by and through the Massachusetts Medicaid program

and other state health care programs, and unaware of the defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third-party payers in connection therewith.

143. Compliance with applicable drug marketing and promotion laws and other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Massachusetts in connection with defendants' fraudulent and illegal practices.

144. Had the State of Massachusetts known that defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third-party payers in connection with defendants' fraudulent and illegal practices.

145. As a result of defendants' violations of Mass. Gen. Laws Ann. 12 § 5B, the State of Massachusetts has been damaged in an amount far in excess of millions of dollars exclusive of interest.

146. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Mass. Gen. Laws Ann. 12 § 5(c)(2) on behalf of himself and the State of Massachusetts.

147. This Court is requested to accept pendan juris over this related state claim as its is predicated upon the same facts as the federal claim and merely asserts separate damages to the State of Massachusetts in the operation of its Medicaid program.

COUNT FOUR

(CALIFORNIA FALSE CLAIMS ACT)

148. Relator repeats and realleges each allegation contained in Counts One, Two and

Three above as if fully set forth herein.

149. This is a *qui tam* action brought by Relator and the State of California to recover treble damages and civil penalties under the California Federal False Claims Act, Cal. Gov't. Code § 12650 *et seq.*

150. Cal. Gov't Code § 12651(a) provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;

(3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or any political subdivision;

(4) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

151. Defendants violated California laws by knowingly allowing hundreds of thousands of false claims to be submitted and presented to the State of California for a substantial period of time by off-label marketing and promotion of their products.

152. The State of California, by and through the California Medicaid program and other state health care programs, and unaware of defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third-party payers in connection therewith.

153. Compliance with applicable Medicare, Medi-Cal and various other federal and state laws was an implied, and upon information and belief, also an express condition of payment

of claims submitted to the State of California in connection with defendants' fraudulent and illegal practices.

154. Had the State of California known that defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third-party payers in connection with defendants' fraudulent and illegal practices.

155. As a result of defendants' violations of Cal. Gov't Code § 12651(a), the State of California has been damaged in an amount far in excess of millions of dollars exclusive of interest.

156. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of himself and the State of California.

157. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

COUNT FIVE

(HAWAII FALSE CLAIMS ACT)

158. Relator repeats and realleges each allegation contained in Counts One through Four above as if fully set forth herein.

159. This is a *qui tam* action brought by Relator and the State of Hawaii to recover treble damages and civil penalties under the Hawaii Federal False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*

160. Haw. Rev. Stat. § 661-21(a) provides liability for any person who:

1. knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;

2. knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

3. conspires to defraud the state by getting a false or fraudulent claim allowed or paid; or

4. is a beneficiary of an inadvertent submission of a false claim to the State, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the State within a reasonable time after discovery of the false claim.

161. Defendants violated Haw. Rev. Stat. § 661-21(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Hawaii for a substantial period of time by off-label marketing and promotion of their products.

162. The State of Hawaii, by and through the Hawaii Medicaid program and other state health care programs, and unaware of defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third-party payers in connection therewith.

163. Compliance with applicable Medicare, Medi-Cal and various other federal and

state laws was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Hawaii in connection with defendants' fraudulent and illegal practices.

164. Had the State of Hawaii known that defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third-party payers in connection with defendants' fraudulent and illegal practices.

165. As a result of defendants' violations of Haw. Rev. Stat. § 661-21(a), the State of Hawaii has been damaged in an amount far in excess of millions of dollars exclusive of interest.

166. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of himself and the State of Hawaii.

167. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Hawaii in the operation of its Medicaid program.

COUNT SIX

(ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT)

168. Relator repeats and realleges each allegation contained in Counts One through Five above as if fully set forth herein.

169. This is a *qui tam* action brought by Relator and the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq*.

170. 740 ILCS 175/3(a) provides liability for any person who:

1. knowingly presents, or causes to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval;

2. knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

3. conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

171. Defendants violated 740 ILCS 175/3(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Illinois for a substantial period of time by off-label marketing and promotion of their products.

172. The State of Illinois, by and through the Illinois Medicaid program and other state health care programs, and unaware of defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third-party payers in connection therewith.

173. Compliance with applicable Medicare, Medicaid and various other federal and state laws was implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Illinois in connection with defendants' fraudulent and illegal practices.

174. Had the State of Illinois known that defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third-party payers in connection with defendants' fraudulent and illegal practices.

175. As a result of defendants' violation of 740 ILCS 175/3(a), the State of Illinois has been damaged in an amount far in excess of millions of dollars exclusive of interest.

176. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 740 ILCS 175/3(b) on

behalf of himself and the State of Illinois.

177. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

COUNT SEVEN

(FLORIDA FALSE CLAIMS ACT)

178. Relator repeats and realleges each allegation contained in Counts One through Six above as if fully set forth herein.

179. This is a *qui tam* action brought by Relator and the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*

180. Fla. Stat. § 68.082(2) provides liability for any person who:

(a) knowingly presents, or causes to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;

(c) conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid.

181. Defendants violated Fla. Stat. § 68.082(2) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Florida for a substantial period of time by off-label marketing and promotion of their products.

182. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, and unaware of defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third-party payers in connection therewith.

183. Compliance with applicable Medicare, Medicaid and various other federal and

state laws was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Florida in connection with defendants' fraudulent and illegal practices.

184. Had the State of Florida known that defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third-party payers in connection with defendants' fraudulent and illegal practices.

185. As a result of defendants' violations of Fla. Stat. § 68.082(2), the State of Florida has been damaged in an amount far in excess of millions of dollars exclusive of interest.

186. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of himself and the State of Florida.

187. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

COUNT EIGHT

(NEW YORK FALSE CLAIMS ACT)

188. Relator repeats and realleges each allegation contained in Counts One through Seven above as if fully set forth herein.

189. This is a *qui tam* action brought by Relator and the State of New York to recover damages and civil penalties under the New York State False Claims Act, Title 13 § 187, *et seq.*

190. Title 13 § 189(1) provides liability for any person who:

> 1. knowingly presents, or causes to be presented, to any employee, officer or agent of the state of a local government, a false or fraudulent claim for

payment or approval;

2. knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a local government;

3. conspires to defraud the state or a local government by getting a false or fraudulent claim allowed or paid.

191. Defendants violated Title 13 § 189(1), and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New York for a substantial period of time by off-label marketing and promotion of their products.

192. The State of New York, by and through the New York Medicaid program and other state healthcare programs, and unaware of defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third-party payers in connection therewith.

193. Compliance with applicable Medicare, Medicaid and various other federal and state laws was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New York in connection with defendants' fraudulent and illegal practices.

194. Had the State of New York known that defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third-party payers in connection with defendants' fraudulent and illegal practices.

195. As a result of defendants' violations of Title 13 § 187(1), *et seq.*, the State of New York has been damaged in an amount far in excess of millions of dollars exclusive of interest.

196. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Title 13 § 187(1), *et seq.* on behalf of himself and the State of New York.

197. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

COUNT NINE

(TEXAS FALSE CLAIMS ACT)

198. Relator repeats and realleges each allegation contained in Counts One through Eight above as if fully set forth herein.

199. This is a *qui tam* action brought by Relator and the State of Texas to recover double damages and civil penalties under V.T.C.A. Hum. Res. Code § 36.001 *et seq.*

200. V.T.C.A. Hum. Res. Code § 36.002 provides liability for any person who:

(1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact;

(a) on an application for a contract, benefit, or payment under the Medicaid program; or

(b) that is intended to be used to determine its eligibility for a benefit or payment under the Medicaid program.

(2) knowingly or intentionally concealing or failing to disclose an event:

(a) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of:

(i) the person; or

(ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and

(b) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;

(3) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:

(a) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program.

201. Defendants violated V.T.C.A. Hum. Res. Code § 36.002 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Texas for a substantial period of time by off-label marketing and promotion of their products.

202. The State of Texas, by and through the Texas Medicaid program and other state health care programs, and unaware of defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third-party payers in connection therewith.

203. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Texas in connection with defendants' fraudulent and illegal practices.

204. Had the State of Texas known that defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third-party payers in connection with defendants' fraudulent and illegal practices.

205. As a result of defendants' violations of V.T.C.A. Hum. Res. Code § 36.002, the State of Texas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

206. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to V.T.C.A. Hum. Res. Code

§ 36.101 on behalf of himself and the State of Texas.

207. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

COUNT TEN

(TENNESSEE FALSE CLAIMS ACT)

208. Relator repeats and realleges each allegation contained in Counts One through Nine above as if fully set forth herein.

209. This is a *qui tam* action brought by Relator and the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq*.

210. § 71-5-182(a)(1) provides liability for any person who:

1. presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;

2. makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;

3. conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent.

211. Defendants violated Tenn. Code Ann. § 71-5-182(a)(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Tennessee for a substantial period of time by off-label marketing and promotion of their products.

212. Defendants' violations of § 71-5-182 and various other federal and state laws caused false claims to be submitted for payment to the State of Tennessee.

213. The State of Tennessee, by and through the Tennessee Medicaid program and other state health care programs, and unaware of defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third-party payers in connection therewith.

214. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Tennessee in connection with defendants' fraudulent and illegal practices.

215. Had the State of Tennessee known that defendants violated the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third-party payers in connection with defendants' fraudulent and illegal practices.

216. As a result of defendants' violations of Tenn. Code Ann. § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive of interest.

217. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1) on behalf of himself and the State of Tennessee.

218. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

COUNT ELEVEN

(DELAWARE FALSE CLAIMS AND REPORTING ACT)

219. Relator repeats and realleges each allegation contained in Counts One through Ten above as if fully set forth herein.

220. This is a *qui tam* action brought by Relator and the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

221. 6 Del. C. § 1201(a) provides liability for any person who:

(1) knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; or

(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

222. Defendants violated 6 Del. C. § 1201(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Delaware for a substantial period of time by off-label marketing and promotion of their products.

223. The State of Delaware, by and through the Delaware Medicaid program and other state health care programs, and unaware of defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third-party payers in connection therewith.

224. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Delaware in connection with defendants' fraudulent and illegal practices.

225. Had the State of Delaware known that defendants were violating the federal and

state laws cited herein, it would not have paid the claims submitted by health care providers and third-party payers in connection with defendants' fraudulent and illegal practices.

226. As a result of defendants' violations of 6 Del. C. § 1201(a), the State of Delaware has been damaged in an amount far in excess of millions of dollars exclusive of interest.

227. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 6 Del. C. § 1203(b) on behalf of himself and the State of Delaware.

228. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Delaware in the operation of its Medicaid program.

COUNT TWELVE

(LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW)

229. Relator repeats and realleges each allegation contained in Counts One through Eleven above as if fully set forth herein.

230. This is a *qui tam* action brought by Relator and the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 437.1 *et seq.*

231. La. Rev. Stat. Ann. § 438.3 provides:

> 1. No person shall knowingly present or cause to be presented a false or fraudulent claim;
>
> 2. No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds;
>
> 3. No person shall conspire to defraud, or attempt to defraud, the medical assistance program through misrepresentation or by obtaining, or

attempting to obtain, payment for a false or fraudulent claim.

232. Defendants violated La. Rev. Stat. Ann. §438.3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Louisiana for a substantial period of time by off-label marketing and promotion of their products.

233. The State of Louisiana, by and through the Louisiana Medicaid program and other state health care programs, and unaware of defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third-party payers in connection therewith.

234. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Louisiana in connection with defendants' fraudulent and illegal practices.

235. Had the State of Louisiana known that defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third-party payers in connection with defendants' fraudulent and illegal practices.

236. As a result of defendants' violations of La. Rev. Stat. Ann. § 438.3, the State of Louisiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

237. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. Ann. § 439.1(A) on behalf of himself and the State of Louisiana.

238. This Court is requested to accept pendant jurisdiction of this related claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to

the State of Louisiana in the operation of its Medicaid program.

COUNT THIRTEEN

(NEVADA FALSE CLAIMS ACT)

239. Relator repeats and realleges each allegation contained in Counts One through Twelve above as if fully set forth herein.

240. This is a *qui tam* action brought by Relator and the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, N.R.S. § 357.010, *et seq.*

241. N.R.S. § 357.040(1) provides liability for any person who:

(a) knowingly presents or causes to be presented a false claim for payment or approval;

(b) knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim;

(c) conspires to defraud by obtaining allowance or payment of a false claim;

(d) is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the state or political subdivision within a reasonable time.

242. In addition, N.R.S. § 422.560 prohibits the solicitation, acceptance or receipt of anything of value in connection with the provision of medical goods or services for which payment may be made in whole or in part under the Nevada Medicaid program.

243. Defendants violated N.R.S. § 357.040(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Nevada for a substantial period of time by off-label marketing and promotion of their products.

244. The State of Nevada, by and through the Nevada Medicaid program and other state health care programs, and unaware of defendants' fraudulent and illegal practices, paid the

claims submitted by health care providers and third-party payers in connection therewith.

245. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Nevada in connection with defendants' fraudulent and illegal practices.

246. Had the State of Nevada known that defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third-party payers in connection with defendants' fraudulent and illegal practices.

247. As a result of defendants' violations of N.R.S. § 357.040(1), the State of Nevada has been damaged in an amount far in excess of millions of dollars exclusive of interest.

248. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.R.S. § 357.080(1) on behalf of himself and the State of Nevada.

249. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

COUNT FOURTEEN

(DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT)

250. Relator repeats and realleges each allegation contained in Counts One through Thirteen above as if fully set forth herein.

251. This is a *qui tam* action brought by Relator and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform

Amendment Act, D.C. Code § 2-308.13 *et seq.*

252. D.C. Code § 2-308.14(a) provides liability for any person who:

1. knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;

2. knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;

3. conspires to defraud the District by getting a false claim allowed or paid by the District;

4. is the beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District.

253. Defendants violated D.C. Code § 2-308.14(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the District of Columbia for a substantial period of time by off-label marketing and promotion of their products.

254. The District of Columbia, by and through the District of Columbia Medicaid program and other state health care programs, and unaware of defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third-party payers in connection therewith.

255. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the District of Columbia in connection with defendants' fraudulent and illegal practices.

256. Had the District of Columbia known that defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third-party payers in connection with defendants' fraudulent and illegal practices.

257. As a result of defendants' violations of D.C. Code § 2-308.14(a), the District of Columbia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

258. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of himself and the District of Columbia.

259. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

COUNT FIFTEEN

(NEW YORK CITY FALSE CLAIMS ACT)

260. Relator repeats and realleges each allegation contained in Counts One through Fourteen above as if fully set forth herein.

261. This is a *qui tam* action brought by Relator and the City of New York to recover damages and civil penalties under the New York City Administrative Code § 7-801, *et seq.*

262. New York City Administrative Code § 7-803 provides liability for any person who:

1. knowingly presents, or causes to be presented, to an city officer or employee a false claim for payment or approval by the city;

2. knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the city;

3. conspires to defraud the city by getting a false claim allowed or paid by the city;

263. Defendants violated the New York City Administrative Code § 7-803 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the City of New York for a substantial period of time by off-label marketing and promotion of their products.

264. The City of New York, by and through the City of New York's Medicaid program and other state health care programs, and unaware of defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third-party payers in connection therewith.

265. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the City of New York in connection with defendants' fraudulent and illegal practices.

266. Had the City of New York known that defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third-party payers in connection with defendants' fraudulent and illegal practices.

267. As a result of defendants' violations of the New York City Administrative Code § 7-803, the City of New York has been damaged in an amount far in excess of millions of dollars exclusive of interest.

268. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the New York City Administrative Code § 7-803 on behalf of himself and the City of New York.

269. This Court is requested to accept pendant jurisdiction of this related state claim as

it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the City of New York in the operation of its Medicaid program.

PRAYER FOR RELIEF

FIRST CAUSE OF ACTION

270. Judgment be ordered against the defendants in an amount equal to three times the damages sustained by the United States as a result of defendants' conduct;

271. A civil penalty be assessed of not less than five thousand, five hundred dollars ($5,500.00) and not more than eleven thousand dollars ($11,000.00) for each violation of 31 *U.S.C.* § 3729;

272. That Relator be awarded the maximum amount allowed pursuant to 31 *U.S.C.* § 3730(d) and/or any other applicable provision of law; and

273. Attorneys' fees and costs according to proof.

SECOND CAUSE OF ACTION

274. Judgment be ordered against the defendants in an amount equal to three times the damages sustained by the United States as a result of defendants' conduct;

275. A civil penalty be assessed of not less than five thousand, five hundred dollars ($5,500.00) and not more than eleven thousand dollars ($11,000.00) for each violation of 42 *U.S.C.* § 1320(a)-7b(b)(2);

276. That Relator be awarded the maximum amount allowed pursuant to 42 *U.S.C.* § 1320(a)-7b(b)(2) and/or any other applicable provision of law; and

277. Attorneys' fees and costs according to proof.

THIRD CAUSE OF ACTION

For the STATE OF MASSACHUSETTS:

278. Three times the amount of actual damages which the State of Massachusetts has sustained as a result of defendants' fraudulent and illegal practices;

279. A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which defendants caused to be presented to the State of Massachusetts;

280. Prejudgment interest; and

281. All costs incurred in bringing this action.

For the RELATOR, William C. Jensen:

282. The maximum amount allowed pursuant to Mass. Gen. Laws Ann. 12 § 5(A) and/or any applicable provision of law;

283. Reimbursement for reasonable expenses which Relator incurred in connection with this action; and

284. An award of reasonable attorneys' fees and costs.

FOURTH CAUSE OF ACTION

For the STATE OF CALIFORNIA:

285. Three times the amount of actual damages which the State of California has sustained as a result of defendants' fraudulent and illegal practices;

286. A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which defendants caused to be presented to the State of California;

287. Prejudgment interest; and

288. All costs incurred in bringing this action.

For the RELATOR, William C. Jensen:

289. The maximum amount allowed pursuant to Cal. Gov't Code § 12650 and/or any applicable provision of law;

290. Reimbursement for reasonable expenses which Relator incurred in connection with this action; and

291. An award of reasonable attorneys' fees and costs.

FIFTH CAUSE OF ACTION

For the STATE OF HAWAII:

292. Three times the amount of actual damages which the State of Hawaii has sustained as a result of defendants' fraudulent and illegal practices;

293. A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which defendants caused to be presented to the State of Hawaii;

294. Prejudgment interest; and

295. All costs incurred in bringing this action.

For the RELATOR, William C. Jensen:

296. The maximum amount allowed pursuant to Haw. Rev. Stat. § 661-21 and/or any applicable provision of law;

297. Reimbursement for reasonable expenses which Relator incurred in connection with this action; and

298. An award of reasonable attorneys' fees and costs.

SIXTH CAUSE OF ACTION

For the STATE OF ILLINOIS:

299. Three times the amount of actual damages which the State of Illinois has

sustained as a result of defendants' fraudulent and illegal practices;

300. A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which defendants caused to be presented to the State of Illinois;

301. Prejudgment interest; and

302. All costs incurred in bringing this action.

For the RELATOR, William C. Jensen:

303. The maximum amount allowed pursuant to 740 ILCS 175 and/or any applicable provision of law;

304. Reimbursement for reasonable expenses which Relator incurred in connection with this action; and

305. An award of reasonable attorneys' fees and costs.

SEVENTH CAUSE OF ACTION

For the STATE OF FLORIDA:

306. Three times the amount of actual damages which the State of Florida has sustained as a result of defendants' fraudulent and illegal practices;

307. A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which defendants caused to be presented to the State of Florida;

308. Prejudgment interest; and

309. All costs incurred in bringing this action.

For the RELATOR, William C. Jensen:

310. The maximum amount allowed pursuant to Fla. Stat. § 68.081 and/or any applicable provision of law;

311. Reimbursement for reasonable expenses which Relator incurred in connection with this action; and

312. An award of reasonable attorneys' fees and costs.

EIGHTH CAUSE OF ACTION

For the State of New York

313. Three times the amount of actual damages which the State of New York has sustained as a result of defendants' fraudulent and illegal practices;

314. A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which defendants caused to be presented to the State of New York;

315. Prejudgment interest; and

316. All costs incurred in bringing this action.

For the RELATOR, William C. Jensen:

317. The maximum amount allowed pursuant to New York Title 13 § 187, *et seq.* and/or any applicable provision of law;

318. Reimbursement for reasonable expenses which Relator incurred in connection with this action; and

319. An award of reasonable attorneys' fees and costs.

320. Costs, including attorneys' fees, of a civil action brought to recover any such penalty or damages.

NINTH CAUSE OF ACTION

For the STATE OF TEXAS:

321. Three times the amount of actual damages which the State of Texas has sustained

as a result of defendants' fraudulent and illegal practices;

322. A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which defendants caused to be presented to the State of Texas;

323. Prejudgment interest; and

324. All costs incurred in bringing this action.

For the RELATOR, William C. Jensen:

325. The maximum amount allowed pursuant to Tex. Stat. §V.T.C.A. Hum. Res. Code § 36.001 and/or any applicable provision of law;

326. Reimbursement for reasonable expenses which Relator incurred in connection with this action; and

327. An award of reasonable attorneys' fees and costs.

TENTH CAUSE OF ACTION

For the STATE OF TENNESSEE:

328. Three times the amount of actual damages which the State of Tennessee has sustained as a result of defendants' fraudulent and illegal practices;

329. A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which defendants caused to be presented to the State of Tennessee;

330. Prejudgment interest; and

331. All costs incurred in bringing this action.

For the RELATOR, William C. Jensen:

332. The maximum amount allowed pursuant to Tenn. Code Ann. §§ 71-5-181 and/or any applicable provision of law;

333. Reimbursement for reasonable expenses which Relator incurred in connection with this action; and

334. An award of reasonable attorneys' fees and costs.

ELEVENTH CAUSE OF ACTION

For the STATE OF DELAWARE:

335. Three times the amount of actual damages which the State of Delaware has sustained as a result of defendants' fraudulent and illegal practices;

336. A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which defendants caused to be presented to the State of Delaware;

337. Prejudgment interest; and

338. All costs incurred in bringing this action.

For the RELATOR, William C. Jensen:

339. The maximum amount allowed pursuant to Title 6, Chapter 12 of the Delaware Code and/or any applicable provision of law;

340. Reimbursement for reasonable expenses which Relator incurred in connection with this action; and

341. An award of reasonable attorneys' fees and costs.

TWELFTH CAUSE OF ACTION

For the STATE OF LOUISIANA:

342. Three times the amount of actual damages which the State of Louisiana has sustained as a result of defendants' fraudulent and illegal practices;

343. A civil penalty of not less than $5,000 and not more than $10,000 for each false

claim which defendants caused to be presented to the State of Louisiana;

344. Prejudgment interest; and

345. All costs incurred in bringing this action.

For the RELATOR, William C. Jensen:

346. The maximum amount allowed pursuant to La. Rev. Stat. Ann. § 437.1 and/or any applicable provision of law;

347. Reimbursement for reasonable expenses which Relator incurred in connection with this action; and

348. An award of reasonable attorneys' fees and costs.

THIRTEENTH CAUSE OF ACTION

For the STATE OF NEVADA:

349. Three times the amount of actual damages which the State of Nevada has sustained as a result of defendants' fraudulent and illegal practices;

350. A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which defendants caused to be presented to the State of Nevada;

351. Prejudgment interest; and

352. All costs incurred in bringing this action.

For the RELATOR, William C. Jensen:

353. The maximum amount allowed pursuant to N.R.S. § 357.010 and/or any applicable provision of law;

354. Reimbursement for reasonable expenses which Relator incurred in connection with this action; and

355. An award of reasonable attorneys' fees and costs.

FOURTEENTH CAUSE OF ACTION

For the DISTRICT OF COLUMBIA:

356. Three times the amount of actual damages which the District of Columbia has sustained as a result of defendants' fraudulent and illegal practices;

357. A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which defendants caused to be presented to the District of Columbia;

358. Prejudgment interest; and

359. All costs incurred in bringing this action.

For the RELATOR, William C. Jensen:

360. The maximum amount allowed pursuant to D.C. Code § 2-308.13 and/or any applicable provision of law;

361. Reimbursement for reasonable expenses which Relator incurred in connection with this action; and

362. An award of reasonable attorneys' fees and costs.

FIFTEENTH CAUSE OF ACTION

For the CITY OF NEW YORK:

363. Three times the amount of actual damages which the City of New York has sustained as a result of defendants' fraudulent and illegal practices;

364. A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which defendants caused to be presented to the City of New York;

365. Prejudgment interest; and

366. All costs incurred in bringing this action.

For the RELATOR, William C. Jensen:

367. The maximum amount allowed pursuant to New York Administrative Code § 7-803 and/or any applicable provision of law;

368. Reimbursement for reasonable expenses which Relator incurred in connection with this action; and

369. An award of reasonable attorneys' fees and costs;

370. Costs, expenses and attorneys' fees of a civil enforcement action and for the cost of the city's investigation.

FOR ALL CAUSES OF ACTION

371. Such other and further relief as the Court deems proper.

BY: /s/ *Neil Mullin*

NEIL MULLIN (NM-6020)
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nmullin@smithmullin.com

Attorneys for Relator, William C. Jensen

DATED: May 14, 2007

DEMAND FOR JURY TRIAL

Relator hereby demands a jury trial.

BY: /s/ *Neil Mullin*

NEIL MULLIN (NM-6020)
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nmullin@smithmullin.com

Attorneys for Relator, William C. Jensen

DATED: May 14, 2007

CERTIFICATION OF SERVICE

The undersigned certifies that on May 14, 2007, a copy of the foregoing COMPLAINT FOR VIOLATION OF THE FEDERAL FALSE CLAIMS ACT AND VARIOUS STATE FALSE CLAIMS ACTS were sent via Federal Express addressed to:

Hon. Christopher J. Christie
United States Attorney
District of New Jersey
970 Broad Street
Newark, New Jersey 07102

Hon. Alberto R. Gonzales
United States Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, N.W.
Room 4545
Washington, D.C. 20530-0001

BY: /s/ *Neil Mullin*

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Attorneys for Relator, William C. Jensen

DATED: May 14, 2007